IMDRF International Medical Device Regulators Forum

Medical Device Single Audit Program (MDSAP) Pilot Update

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MDSAP Pilot Consortium

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Observers

- *03/2013*: Accelerated plan to develop the basic structure for the 3 year pilot program starting on 01/01/2014

- *Pilot started **13** eligible Auditing Organizations Acredited under the CMDCAS – Canadian Medical Device Conformity Assesment System*

AOs Authorized to Perform MDSAP Audits

1 - BSI Group America Inc.
2 - TŰV SŰD America Inc.
3 - SAI Global Cert. Services PTY Ltd.
4 - LNE G-MED
5 - TŰV USA Inc.
6 - Intertek Testing Services NA Inc.

AOs Audit Progress

Approximately fifty-eight (58) MDSAP audits of medical device manufacturers have been conducted up to Feb 15 2016

AOs Under Authorization Process

1- UL, LLC
2- DQS MED GmbH
3- NSAI
4- TŰV Rheinland of NA Inc.
5 - DEKRA Certification B.V.
6 - SGS UK Ltd.
7- LRQA Inc.

Perspectives

It is anticipated that all application reviews and assessments for Authorization purposes will be completed for all eligible CMDCAS registrars prior to the conclusion of the MDSAP Pilot.

Perspectives

It is feasible that most of the auditing organizations will complete all prerequisite MDSAP recognition requirements prior to 31 December 2016. As of 01 January 2017, MDSAP will be open to additional Auditing Organization applicants outside of the Health Canada CMDCAS registrars.

Remarks from Dec 2015

Health Canada Announcement on the transition plan from CMDCAS to MDSAP

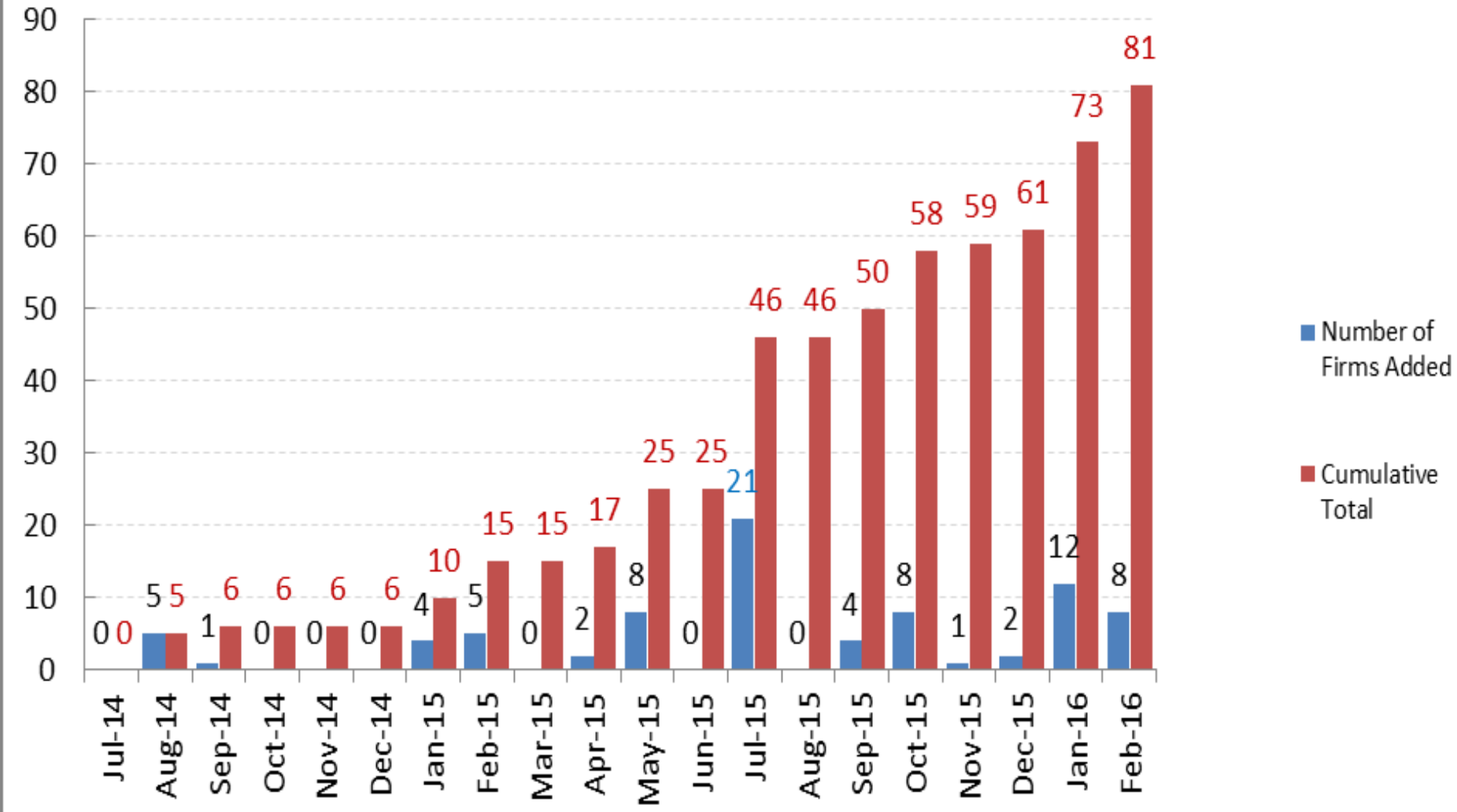
Only MDSAP certificates will be accepted after **Dec. 31 2018.**

Remarks from Dec 2015

ANVISA issuance of the first GMP certificate based on the outcome of the program

US FDA Announcement on the participation in the operational phase of MDSAP

MDSAP Participating Manufacturer Sites



Perspectives

As more AOs become authorized to conduct MDSAP audits, a continuation of the positive slope for the manufacturers commitment to the program is anticipated.

Program participation by medical device manufacturers continues to be the primary challenge for the pilot at this point.

Thank you

The Pilot is full steam and it ends when the program becomes fully operational!